

**REMARKS**

Claims 32 – 37 are pending in this case and stand rejected in a final Office Action mailed December 8, 2008. Claims 1-14 were previously canceled, and claims 15-31 were previously withdrawn from consideration in view of a restriction requirement.

**Examiner's Withdrawal of Claims 38 and 39**

Claims 38 and 39 stand as withdrawn pursuant to the Examiner's statement in the December 8, 2008 Office Action, Status of the Application. Applicants respectfully object to and traverse the constructive election by the Examiner and the withdrawal claims 38 and 39 from consideration in this application. The Applicants traverse this restriction since the claimed subject matter is an obvious variant of the use of the other claims as previously presented. The subject matter of claims 38 and 39 is similar enough to the pending claims that to require additional patent applications, and the resulting patents, for this closely related subject matter would result in a burden on the PTO, the Applicants, and the public. The PTO would be burdened by having to handle an additional patent application file and to assign an Examiner to do a separate search and examination. This would add to the backlog of cases at the PTO. Applicants would be burdened by having to pay additional fees and expend additional efforts in prosecuting the additional applications. The public would be burdened by having to consider a plurality of patents instead of one in any infringement or freedom to operate analysis.

For the foregoing reasons, Applicants request withdrawal of the imposed restriction. In the event that the Examiner denies the request for withdrawal of the restriction requirement, Applicants believe that claims 32-37 are in condition for allowance and request prompt examination and allowance of claims 32-37.

### **Amended Claims**

Amended independent claims 32 and 36 are presented for the Examiner's consideration. Applicants have replaced the "comprising" language with "consisting of" and have inserted "non-saccharide" in front of the newly added excipients limitation to remove any doubt that the claimed compositions encompass only compositions that contain a single saccharide.

Applicants believe that these amended claims further point out and distinguish Applicants' invention. Applicants respectfully request that the Examiner consider these proposed amendments and allow amended independent claims 32, 36 and 38 and the dependent claims which variously depend from these claims.

### **Rejection Under 35 USC §103 – Mizumoto in view of Mauger**

Claims 32-37 stand rejected under 35 USC §103 over Mizumoto et al. (US 5,576,014, herein "Mizumoto") in view of Mauger et al. (US 5,728,403, herein "Mauger").

Applicants assert that the Examiner's bases for this rejection has been removed in light of the amended claims as presented. By amending to include consisting of language, the current claim amendments unequivocally specify that the claimed compositions consist of a single saccharide.

Applicants further disagree that there is any disclosure in Mizumoto of compositions with a single saccharide having the requisite advantages per the claims as presently submitted. Indeed, a primary conclusion of Mizumoto is that "when a saccharide having low moldability or a saccharide having high moldability was used alone in the compression molding, the adequate hardness and the quick disintegration and dissolution in the buccal cavity were not simultaneously obtained." Col. 5, lines 18-22. As such, in context, Mizumoto teaches away from compositions as claimed herein.

Further, the citation to definitions at Column 6 is misplaced. The Examiner points to the definitions of the terms "saccharide having low moldability" and "saccharide having high moldability" as potentially including only a single saccharide. However, when these terms are used elsewhere in the specification,

they are always used in combinations wherein more than one saccharide must be present. See Mizumoto column 12, line 24 through column 13, line 15.

Further, contrary to the Examiner's assertion, no examples in Mizumoto include only one saccharide. The chart below shows the multiple saccharides present in the individual examples:

<u>Example</u>	<u>Saccharides</u>
1	maltose and mannitol
2	maltitol and mannitol
3	sorbitol and mannitol
4	maltose and lactose
5	oligosaccharide and mannitol
6	lactose, mannitol and maltitol
7	maltose and glucose
8	maltose and xylitol
9	maltose and sucrose
10	mannitol and lactose
11	lactose, mannitol and maltose
12	maltose and mannitol
13	maltose and mannitol
14	maltose and mannitol
15	maltose, mannitol and lactose
16	maltose and mannitol
17	maltose, mannitol and lactose
18	maltose and mannitol
19	maltose and mannitol (from Ex. 18) and more mannitol

As such, Mizumoto neither teaches or suggests that one saccharide is required (Mizumoto requires at least two saccharides with specified moldabilities). Mizumoto stresses the importance of having both a low and high moldability saccharides present and teaches that they should be granulated together to get the best characteristics of each (col. 5, lines 52-66). Further Mizumoto neither teaches or suggests that a saccharide and a low melting point compound form a fast dissolve granulation; and/or that a saccharide in combination with a low melting point solid forms a fast dissolving granulation and/or that the fast dissolving granulation comprises about 30% to about 75% of the weight of the fast dissolve tablet as Applicants' claims require.

Mauger also does not disclose or suggest a combination including only a single saccharide. The Examiner stated in the final paragraph of page 4 onto page 5 of the December 8, 2009 Office Action that the Examiner relied upon Mauger “to demonstrate the teaching that it is known to incorporate mixtures of mono-, di- and triglycerides, whereby the glycerides provide for taste-masking of drugs and enables a composition to melt at body temperature.” (emphasis added). Mauger provides no teaching, suggestion, or motivation to use a single saccharide even in the coating disclosed in Mauger much less any other capacity. Further, Mauger provides no teaching disclosure or motivation to use a fast dissolve granulation in a tablet in any capacity coating or otherwise. Accordingly, Mauger does not disclose, suggest or provide motivation for combining saccharide with a low melting point solid form to a fast dissolving granulation, and no teaching, suggestion or motivation for forming a tablet wherein about 30% to about 75% of the weight of the tablet is a fast dissolve granulation of a saccharide and a low melting point solid as Applicants' claims 32 and 38 require.

Thus Mauger neither teaches or suggests the elements needed to cure the identified deficiency of Mizumoto – namely Mauger does not teach or suggest that a single saccharide and a low melting point compound may be used to form a fast dissolving tablet composition and/or that a saccharide in combination with a low melting point solid forms a fast dissolving granulation and/or that the fast dissolving granulation comprises about 30% to about 75% of the weight of the tablet.

In view of at least these distinctions and the fact that Applicants have amended independent Claims 32 and 36 to clarify that only a single saccharide is required in the claims herein, Applicants respectfully request that the Examiner withdraw the rejection of independent claims 32 and 36 and claims 33-35, and 37 which variously depend from claim 33 and 36 under 35 USC §103 over Mizumoto (US 5,178,878) in view of Mauger et al. (US 5,728,403).

#### **Rejection Under 35 USC §103 (a) - Shimizu**

The Examiner has stated that claims 32 and 34-36 stand rejected under 35 USC §103 over Shimizu et al. (U.S. 6,299,904 B1, herein “Shimizu”).

As above, amended independent claims 32 and 36 are presented for the Examiner's consideration. Applicants have replaced the "comprising" language with "consisting of" and have inserted "non-saccharide" in front of the newly added excipients limitation to remove any doubt that the claimed compositions encompass only compositions that contain a single saccharide.

Applicants believe that these amended claims further point out and distinguish Applicants' invention. Applicants respectfully request that the Examiner consider these proposed amendments and allow amended independent claims 32, 36 and 38 and the dependent claims which variously depend from these claims.

The Examiner has cited Col. 8, lines 5-8 of Shimizu for a tablet of hardness of about 2 to about 20 kg. Firstly, this hypothetical disclosure is not supported anywhere in the rest of Shimizu. None of the Shimizu examples have a hardness that comes close to the recited lower boundary of 2 kg. The lowest hardness actually exemplified in Shimizu is 4.2 kg in Working Example 5 (Col. 11, lines 35-36). The hardness range claimed by Applicants is consistent with the hardness measured for exemplary embodiments of Applicants' composition and is substantially lower than what is meaningfully disclosed by Shimizu. One skilled in the art recognizes that tablet hardness may impact a number of properties of a tablet including for example, processability, robustness and dissolution behavior. As the data presented in Example 8 shows, Applicants' composition can be formed into a tablet with substantially lower hardness than that of Shimizu.

Nonetheless, despite the failure by Shimizu to meaningfully enable one of skill in the art to create tablets with a hardness below 4.2 kg, the presently presented claims are directly to tablets with a hardness less than about 1.7 kP.

Furthermore, nowhere does Shimizu disclose or suggest the combination of a single saccharide and low melting point compound to form a fast dissolving granulation. Shimizu teaches a combination of one or more of a limited number of sugar alcohols with a very hygroscopic material hydroxypropylcellulose. Nowhere does Shimizu teach or suggest a fast dissolve granulation of a low melting point compound and a saccharide and/or that such a granulation should comprise about 30% to about 70% of the tablet by weight and/or that the amount of low melting point compound should be about 0.01% to about 2.5% (wt/wt) of the tablet. Accordingly,

Shimizu does not set forth or infer every claim element of Applicants' claim 32. Nor does Shimizu provided any suggestion or motivation to prepare a fast dissolve granulation much less a fast dissolve granulation as described and claimed by applicants.

As claims 34 and 35 variously depend from claim 32, the present amendment to claim 32 reciting a hardness of less than about 1.7 kP applies to claims 34-35. Accordingly, the amendment also further distinguishes claims 34-35 from Shimizu for the reasons discussed above.

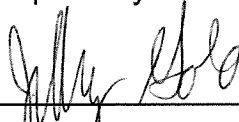
With respect to claim 36, Shimizu does not teach the claimed limitation requiring that the low melting point compound be selected from hydrogenated vegetable oil, and partially hydrogenated vegetable oil. Indeed, Shimizu does not recognize the advantage of a low melting point compound at all, let alone the specifically claimed compounds herein.

In view of at least these distinctions, Applicants respectfully request that the Examiner withdraw the rejection of independent claims 32 and 36 and claims 34 and 35 which depend from claim 32 and under 35 USC §103 over Shimizu et al.

#### **CONCLUSION**

In view of the amended claim set presented herein and the above remarks, Applicants respectfully request that currently presented claims be entered and allowed. Should the Examiner believe that anything further is desired in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicant's representative at 973-660-5739.

Respectively submitted,



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